UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

STEUBEN FOODS, INC.,

Plaintiff,

v.

OYSTAR GROUP, ET AL.,

Defendants.

1:10-cv-00780-EAW-JJM
1:10-cv-00781-EAW-JJM
1:12-cv-00904-EAW-JJM
1:13-cv-00892-EAW-JJM
1:13-cv-01188-EAW-JJM

PLAINTIFF STEUBEN FOODS, INC.'S SUPPLEMENTAL BRIEFING REGARDING IMPACT OF RECENT PTAB DECISION ON PLAINTIFF'S OBJECTIONS TO THE OCTOBER 1, 2018 REPORT AND RECOMMENDATION AND DEFENDANTS' RESPONSES THERETO

The PTAB's May 8, 2019, IPR Decision ("Decision")[1] undermines the oxonia machine Defendants' "FDA-approved sterilant" argument, raised as an alternative to the written description analysis in the October 1, 2018 R & R. Those "Oxonia Defendants" raised that argument in an attempt to remove the explicitly disclosed and claimed oxonia sterilant from the scope of Steuben's patents. "While the PTAB's constructions will not be binding on this court, the IPR[s] will inform this court's ultimate reasoning." *Evolutionary Intelligence, LLC v. Sprint Nextel Corp.*, No. C-13-04513, 2014 WL 4802426, at *4 (N.D. Cal. Sept. 26, 2014).[2]

The Decision recognizes (at 12) that "the Federal Circuit determined that the specification's definition of 'aseptic' as 'the United States FDA level of aseptic,' was 'binding lexicography.'" Notably absent from the Decision's identification of the lexicography is any suggestion that the lexicography includes the use of an "FDA-approved sterilant." While not part of its written description findings, the R & R (at 3) suggested that Steuben had stated that the Background of the Invention's reference to "FDA-approved sterilant" was "an example of the 'lexicography.'" The Oxonia Defendants advocate for such a finding now as a matter of claim construction. However, the PTAB in addressing the same brief cited in the R & R did not find those statements to be part of the lexicography, and neither had the Federal Circuit. Indeed, in the brief cited in the R & R, Steuben noted that there were "multiple instances of clear lexicography" such that "the term 'aseptic' must be interpreted to require the FDA level of aseptic." [12-cv-904,

[1] The Decision [Dkt. 568-1] found claim 20 of the '013 patent patentable and claims 18 and 19 unpatentable. Steuben intends to appeal the PTAB's findings with respect to claims 18 and 19. (Unless otherwise stated, citations to the docket refer to the docket in 12-cv-904.)

[2] The Decision (at, *e.g.*, 11, n.18) applied the "broadest reasonable interpretation" claim construction standard, which is different than the claim construction applied by a district court. While the difference in standards may impact certain claim terms, it does not make a difference with respect to the Oxonia Defendants' FDA-approved sterilant argument. Indeed, during the lengthy *Markman* briefing process, the Oxonia Defendants did not argue that the different claim construction standards impact their FDA approved-sterilant argument and cannot do so now.

Dkt. 427-14 at 33]. The "multiple instances" referred to the fact that the patent twice provides the same lexicographic definition for "aseptic." [*Id*. at 31-32].

The Decision affirmatively rejects the notion that the claims require FDA approval or are limited to the use of hydrogen peroxide. In discussing claim 19 of the '013 patent, which recites "aseptically disinfecting" to a "6 log reduction in spore organisms," the Decision (at 32 (emphasis added)) found that "***claim 19 does not require the use of hydrogen peroxide or FDA approval.***" Instead, the claims require meeting the "FDA level of aseptic," which can be met prior to and/or without obtaining FDA approval. Indeed, that is the entire premise of the invention: "The present invention provides an aseptic processing apparatus that ***will meet*** the stringent FDA [] requirements . . . ." '013 patent at 4:24-26 (emphasis added). The invention is directed to methods to meet the FDA level of aseptic, not methods that have ***already met*** that approval. [*See, e.g.*, Dkt. 492 at 19-24, 30-33]. For that reason, among others, the PTAB correctly found that the claims are not limited to hydrogen peroxide.

In considering what was and was not understood and obvious to persons of ordinary skill, the Decision (at 32) states that Steuben's "argument that hydrogen peroxide was the only FDA-approved sterilant at the time of filing, and that to achieve FDA levels of sterility for this sterilant, the test organism is *bacillus subtilis*, is not sufficiently persuasive." In the cited statement, Steuben explained that the prior art disclosed that where hydrogen peroxide was used as the sterilant, the FDA required the use of *bacillus subtilis* as the test organism to demonstrate sterility due to that organism's resistance to hydrogen peroxide. [Dkt. 427-14 at 40-45].

Steuben did not argue that its invention required the use of hydrogen peroxide, but rather argued that "the relevant question" was whether the prior art system "achieved a 6 log reduction in *bacillus subtilis*" because the ***prior art*** "used [] hydrogen peroxide." [*Id*. at 44]. Hydrogen

peroxide and *bacillus subtilis* were at issue in the IPR because the prior art used hydrogen peroxide—not because Steuben argued its claims were limited to hydrogen peroxide. GEA has cited that argument as a "disclaimer" limiting the invention itself to the use of hydrogen peroxide. As the PTAB correctly found, Steuben did not limit its claims to require hydrogen peroxide through that statement or otherwise.

Furthermore, the Decision (at 12 (emphases added)) notes that the Federal Circuit vacated a prior PTAB decision in the same proceeding because "[t]he Federal Circuit concluded that our construction of 'aseptic' as incorporating '***any applicable United States FDA standard***' rather than only FDA regulations governing 'aseptic packaging' ***was erroneous***." Here, despite the Federal Circuit's finding, GEA has argued that "'***[a]septically disinfecting' requires compliance with all FDA aseptic standards***, including § 348, and not just the regulations." [Dkt. 559 at 4 (emphasis added)]. But "aseptic" does not include § 348 because it applies to all foods. [*See* Dkt. 568-1 at 32, n.25]. The Decision thus rebuts GEA's attempt to read § 348 into the construction of "aseptic" as a requirement limiting the claims to the use of an FDA-approved sterilant.

Thus, the Decision confirms that the Court should not adopt the Oxonia Defendants claim construction arguments, presented as alternatives to the erroneous written description analysis in the R&R. GEA portrayed these arguments as two paths in its demonstrative presented at the February 26, 2019 Oral Argument. As to the left (red) path, as the Decision found, Steuben has not limited its claims to requiring FDA approval. As to the middle (blue/gray) path, the Decision correctly found that only regulations governing aseptic packaging are within the scope of the FDA level of aseptic under the Federal Circuit's construction. Those regulations do not include a sterilant approval requirement. [Dkt. 492 at 7-9]. There is no basis in the patents or regulatory scheme to limit the claims to requiring only sterilants that had been approved on February 2, 1999.

Respectfully submitted,

Dated: May 24, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on May 24, 2019, I caused the foregoing document to be served electronically on Defendants' counsel of record by filing it with the Court's ECF system.

/s/ Joseph L. Stanganelli
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